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TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
SCHWADRON, RONALD B	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/668,555
Filing Date: September 22, 2000
Appellant(s): VAN OOOSTERHOUT ET AL.

Allen C. Turner
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/9/2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying that there are no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is partially correct. The amendment filed 12/5/2002 was not entered as per appellants comment in this section of the Brief. The Brief does not indicate that the amendment/reply filed 4/23/2003 was entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

WO 89/06967	Scannon	8-1989
6,261,535	Thorpe et al.	7-2001

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A) Claims 1-5,7,8,10-13,15,18,19,21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Scannon et al. (WO 89/06967) .

Scannon et al. teach use of a pharmaceutical composition containing the immunotoxins antiCD3 antibody/ ricin A and antiCD7 antibody/ ricin A to treat GVHD (see page 4, first paragraph, page 6, first paragraph, page 12, page 13). Scannon et al. teach that the immunotoxin can be prepared by chemical linkage (see page 14 and 15). Scannon et al. teach that the composition can contain antibody immunotoxins against

the T cell markers CD3, CD7, CD5 (page 4, first paragraph). The pharmaceutical composition taught by Scannon et al. (see page 10, last paragraph) uses the dosage encompassed by that recited in claims 11 and 12, because said recited dosage is based on the subject's size and the subject could be of any size. Scannon discloses that the antibody can be of the IgG isotype (see page 6, second paragraph) wherein IgG2B is one of the four art known types of IgG. Scannon et al. also discloses use of antibodies of the IgG2B isotype in Table 1 (such as OKT4, etc).

B) Claims 1-8,10-13,15,18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scannon et al. (WO 89/06967) in view of Thorpe et al. (US 6,261,535).

Scannon et al. teach use of a pharmaceutical composition containing the immunotoxins antiCD3 antibody/ ricin A and antiCD7 antibody/ ricin A to treat GVHD (see page 4, first paragraph, page 6, first paragraph, page 12, page 13). Scannon et al. teach that the immunotoxin can be prepared by chemical linkage (see page 14 and 15). Scannon et al. teach that the composition can contain antibody immunotoxins against the T cell markers CD3, CD7, CD5 (page 4, first paragraph). The pharmaceutical composition taught by Scannon et al. (see page 10, last paragraph) uses the dosage encompassed by that recited in claims 11 and 12, because said recited dosage is based on the subject's size and the subject could be of any size. Scannon discloses

that the antibody can be of the IgG isotype (see page 6, second paragraph) wherein IgG2B is one of the four art known types of IgG. Scannon et al. also discloses use of antibodies of the IgG2B isotype in Table 1 (such as OKT4, etc). Scannon et al. do not teach the claimed invention which uses deglycosylated ricin A. Thorpe et al. teach use of deglycosylated ricin A in immunotoxins (see column 2, second paragraph). Thorpe et al. teach that use of deglycosylated ricin A in immunotoxins results in decreased hepatotoxicity (see column 2, second paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Scannon et al. teach the claimed invention except for use of deglycosylated ricin A while Thorpe et al. teach use of deglycosylated ricin A and that use of deglycosylated ricin A in immunotoxins results in decreased hepatotoxicity (see column 2, second paragraph).

(11) Response to Argument

A) Claims 1-5,7,8,10-13,15,18,19,21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Scannon et al. (WO 89/06967) .

Regarding appellants comments and the issue of what "consisting essentially of" means in the context of the claims under consideration, the following comments are made. The MPEP section 2111.03 discloses:

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also > AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.);< In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with

the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.").

The Examiner has argued that "consisting essentially" of as recited in the claims encompasses the use of the antibody immunotoxins recited in the claims in combination with other antibody immunotoxins (as per disclosed by Scannon) whilst appellant argues that it does not. Appellant seems to be arguing that the "basic and novel characteristic of the claimed invention" as disclosed in the specification is the use of antibody immunotoxins specific for the T-cell and NK-cell lineage. **However, this description is clearly erroneous because the specification, page 6, discloses use of antiCD5 antibody in the instant invention, wherein the art recognizes that said antibody reacts with B cells (see Scannon, Table 1 under CD5).** Thus, the specification discloses that the claimed invention can encompass use of antibodies which bind cells other than T cells or NK cells. Furthermore, the WEB site to which appellant refers to in page 6, second paragraph of the Brief , indicates that **CD7 is found on pluripotential hematopoietic stem cells. Thus, even the particular combination of antibody immunotoxins recited in the claim bind cells other than T cells or NK cells.**

Regarding appellants comments, Scannon does not teach that antiCD9 or antiCD11 are necessary for his immunotoxins. Scannon discloses use of the antibodies of Table 1, which do not include antiCD9 or antiCD11. Furthermore, Scannon discloses that a composition of immunotoxins containing antiCD3, antiCD5 and antiCD7 can be used (see claim 7 and page 9, second paragraph) **wherein said combination is also disclosed in page 6 of the specification of the instant invention.** Thus, the disclosed invention in the specification is not specific for T cells and NK cells (encompasses use of antibodies which bind cells other than the aforementioned) and the "basic and novel characteristic of the claimed invention as disclosed in the specification" is not a method which is "precise targeting of cells in the T cell and NK cell lineages".

Furthermore, the composition disclosed in Scannon would have the functional property of "eliminating the number of unwanted CD3 and /or CD7 positive cells" because it contains the antibody immunotoxins recited in the claims (e.g. antiCD3 and antiCD7). Similarly, the method taught by Scannon could be practiced as per claim 15 because it contains the antibodies recited in the claims (eg. antiCD3 and antiCD7).

Regarding appellants arguments that Scannon is not enabled for the immunotoxins recited in the claims, the following comments are made.

Appellant has provided no actual evidence as to why Scannon is not enabled for the production of the antibody immunotoxins recited in the claims. Regarding the speculative comments in pages 8-9 of the Brief, the MPEP section 716.01(c) states

> *II. >< ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE*

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

There is no evidence of record that the antiCD3 and antiCD7 immunotoxins disclosed by Scannon could not be made or used in vivo to treat disease. However, the specification, page 11, penultimate paragraph indicates that the **antiCD7 immunotoxin was known in the art (said passage refers to paper (49) (cited on page 25 of the specification), which was published in 1989)**. Thus, by applicants own admission, antiCD7 immunotoxins had already been produced and were known in the prior art. In addition, the references cited in the specification, pages 22-24 disclose that **antiCD3 immunotoxins were known in the art** (for example, see reference 28). Thus, antiCD3 and antiCD7 immunotoxins were already known and produced in the prior art. In addition, the specification, page 4, first paragraph indicates that the prior art indicated that immunotoxins had already been used in vivo to treat lymphoma. Scannon also discloses use of immunotoxin in vivo to treat human disease (see pages 17-19).

There is no evidence of record that Scannon is not enabled for making and using antiCD3/antiCD7 immunotoxins.

B) Claims 1-8,10-13,15,18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scannon et al. (WO 89/06967) in view of Thorpe et al. (US 6,261,535).

Regarding appellants comments about unexpected results, the following comments are made. The claimed inventions are drawn to in vivo methods and a pharmaceutical composition for in vivo use. There is no evidence of record to suggest any unexpected result that is of the scope of the claimed invention (e.g. unexpected results pertinent to in vivo use). The results which appellant refers to in pages 9 and 10 of the Brief refer to in vitro data. However, the claimed inventions are not drawn to in vitro methods or a composition for in vitro use. Thus, the putative unexpected results are not commensurate in scope with the claimed inventions.

Regarding appellants speculations about the in vivo pertinence of the aforementioned in vitro data, said speculations are unsupported by any evidence of record. The MPEP section 716.01(c) states

II. >< ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

Furthermore, regarding the in vitro and in vivo data disclosed in the specification, van Oosterhout et al. (Blood 2000), filed with the amendment filed 6/11/2002, [said paper includes the in vitro and in vivo disclosed in the specification] states:

> It is impossible from the clinical data to determine the exact contribution of SPV-T3a-dgA and WTI-dgA (or their MoAb moieties) to the observed biologic and clinical responses.

SPV-T3a-dgA and WTI-dgA are the specific antiCD3 and antiCD7 immunotoxins disclosed in the specification. Thus, one of the inventors of the claimed invention states in a publication filed after the filing date of the instant invention that it is impossible from the clinical data to evaluate what the contribution of the two immunotoxins is in vivo. Thus, it is impossible to determine if a synergistic effect was even seen in vivo (in the absence of data related to the in vivo administration of the individual immunotoxins) because it is impossible to evaluate what component of the response is related to either of the two components of the multi immunotoxin cocktail.

Regarding appellants arguments in page 11-14 of the Brief, as per above, the Examiner is interpreting "consisting essentially" as recited in the claims as encompassing use of immunotoxins in addition to antiCD3 immunotoxin and antiCD7 immunotoxin. Scannon et al. teach that the composition can contain antibody immunotoxins against the T cell markers CD3, CD7, CD5 (page 4, first paragraph).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644

October 28, 2004

TRASK BRITT

P.O. BOX 2550

SALT LAKE CITY, UT 84110

Conferees

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

JAMES HOUSEL 10/29/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600